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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 09/440,462  | 11/15/1999  | WALID NAJIB ABOUL-HOSN | 032301-047          | 2975             |
| 7590  | 07/26/2004  |                        | EXAMINER            |                  |
| Daniel D Ryan<br>Ryan Kromholz & Manion S C<br>P O Box 26618<br>Milwaukee, WI 53226 |             |                        | BLANCO, JAVIER G    |                  |
|   |             |                        | ART UNIT            | PAPER NUMBER     |
|   |             |                        |                     | 3738             |

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/440,462             | ABOUL-HOSN ET AL.   |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Javier G. Blanco       | 3738                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 05 April 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-5, 7, 9-18 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 7, 9-18 and 47 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/28/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Drawings***

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Response to Amendment***

2. Applicants' cancellation of claims 6, 8, 19-46, 48, and 49 in the reply filed on April 5, 2004 is acknowledged. Claims 1-5, 7, 9-18, and 47 remain pending in the application.

3. Applicants' filing of a certified copy of International Application PCT/US99/10871 in the reply filed on April 5, 2004 is acknowledged.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 7, 9-18, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola (US 4,985,014; cited in a previous PTO-892) in view of Jarvik (US 5,376,114) and Koros et al. (US 5,167,223).

As seen in Figures 3-6, Orejola discloses a system for circulating blood in a patient (see entire document), the system comprising (i) a cannula assembly comprising an outer cannula (outer tubing 32) and an inner cannula (inner tubing 40) *sized and configured to be* (emphasis

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added) slidably received within the outer cannula, and (ii) a pump (pump 10). The inner and outer cannulas forming between them a lumen (shown in Figures 3-5) defining a first flow path, the inner cannula defining a second flow path and being *sized and configured* (emphasis added) to extend beyond the outer cannula (shown in Figure 3) to provide blood output at a location in a heart chamber (see column 3, lines 35-42).

Orejola does not disclose a priming volume of not greater than about 1000 ml. However, Jarvik teaches a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero in order to aid in simplify management of heart function during the surgical procedure (see column 1, lines 58-64; column 6, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero, as taught by Jarvik, with the system of Orejola, in order to aid in simplify management of heart function during the surgical procedure.

Orejola does not disclose the pump as been coupled to a controller. However, Jarvik teaches a pump coupled to a microprocessor-based controller in order to regulate the flow and pressure of the blood flowing through the cannula (see column 3, lines 29-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump coupled to a controller, as taught by Jarvik, with the system of Orejola, in order to regulate the flow and pressure of the blood flowing through the cannula.

Orejola does not disclose the use of a cradle adapted to support the heart while the surgery is performed. However, Koros et al. teach a cradle (i.e., net) adapted to support the heart

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in order to provide better access to the heart for the surgeon (see Figure 1; column 3, lines 48-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a cradle to support the heart while performing a surgical procedure, as taught by Koros et al., with the system of Orejola, in order to provide better access to the heart for the surgeon.

Regarding the intended use of the device (e.g., “*sized and configured to extend through an incision into the vena cava or the right atrium*”, “*sized and configured to extend through an incision into the pulmonary vein or the left atrium*”, etc.), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1 and 47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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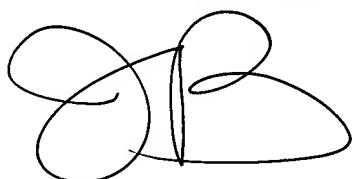
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



July 21, 2004



David H. Willse  
Primary Examiner